V. 510(k) Summary

Submitter

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Date Prepared

January 22, 2004

Trade Name

MedAmicus FlowGuard™ Peelable Introducer

Common Name

Catheter Introducer

Predicate Device

MedAmicus FlowGuard™ Peelable Introducer 510(k) K030905.

Device Description

The MedAmicus FlowGuard™ Peelable Introducer is a small diameter tubular shaped device with integrated proximal handles. The FlowGuard™ Peelable Introducer is designed to provide a relatively atraumatic method for implanting catheters and pacemaker leads into the venous system. The FlowGuard™ Peelable Introducer has a "tear-away" feature common to the predicate devices. This feature allows the user to remove the introducer without removing the inserted catheter or pacing lead. The MedAmicus FlowGuard™ Peelable Introducer is packaged in three configurations: 1) a convenience kit containing a MedAmicus FlowGuard™ Peelable Introducer, a thin-wall needle, a disposable syringe, and a flexible guidewire, packaged in a tray and a sealed pouch. 2) individually pouched, sterile MedAmicus FlowGuard™ Peelable Introducer and 3) bulk, nonsterile MedAmicus FlowGuard™ Peelable Introducers.

Intended Use

There are no changes to the Intended Use of the device from the currently approved device.

The MedAmics FlowGuard™ Peelable Introducer is indicated for use in the percutaneous insertion of pacing leads or catheters in the venous system.

Technological Characteristics

The material revision to the sheath handle material is technologically equivalent to the currently approved device. The method of use is not revised as a result of the material change.

Summary of Studies

Design Verification of the device has been completed to verify the changes to the device. These validations were completed based on a Risk Analysis per internal procedures that are compliant with European Standard EN1441: 1998 Medical Devices -- Risk Analysis. This Risk Analysis was completed by comparing the risks associated with the new material sheath handle compared to the currently approved device. Shelf Life testing, using accelerated aging, has been completed to verify that the new material will yield consistent handle integrity. The validations are summarized in Section X of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2004

MedAmicus Incorporated
c/o Ms. Kary Haskell
Quality Assurance and Regulatory Affairs Manager
15301 Hwy, 55 West
Minneapolis, MN 55447

Re: K040150
MedAmicus FlowGuard Peelable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II (two)
Product Code: DYB
Dated: January 22, 2004
Received: January 23, 2004

Dear Ms. Haskell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040150

Device Name: MedAmicus FlowGuard™ Peelable Introducer

Indications For Use: The MedAmicus FlowGuard Peelable Introducer in indicated for use in the percutaneous insertion of pacing leads or catheters in the venous system.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040150